UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	Master File No. 06 MD 1789 (JFK)
This document relates to: Scheinberg v. Merck & Co., Inc., No. 08 Civ. 4119 (JFK)	OPINION & ORDER

JOHN F. KEENAN, United States District Judge:

Before the Court is a multitude of motions in limine filed by both parties in advance of trial. The Court will address each motion in turn.

I. Plaintiff's Motions in Limine

A. Motion To Preclude Merck from Using Patient Package Insert During Trial, if Dr. Parisian's Testimony on the "Blister-Pack" Is Excluded

Merck represents that it will not introduce any testimony as to the patient package insert unless Plaintiff "opens the door." Since Plaintiff's December 7, 2012 Declaration that she read the patient package insert has been deemed inadmissible because it directly contradicts her deposition testimony (Opinion of Jan. 7, 2013), Plaintiff will be unable to "open the door" in the way Merck predicts. Indeed, as the Court determined in its Daubert opinion, the issue of a blister-pack is not properly in this case. The information that Merck communicated to Plaintiff is irrelevant under New York's

"learned intermediary doctrine." Therefore, the motion is denied as moot.

B. Motion To Preclude Testimony from Dr. Kaplan-Newitz and Dr. Stern Concerning Diabetes and Slow Healing

This motion is denied. If Dr. Kaplan-Newitz has knowledge about the impact of diabetes on healing in the oral cavity, then she is permitted to testify about it. Whether this knowledge impacted her treatment of Scheinberg is for Plaintiff's counsel to explore on cross examination.

As the Court has held in prior bellwethers, testimony of treating doctors about their treatment and diagnosis of Plaintiff, including the opinions they formed during treatment, is admissible. Plaintiff's treating physicians are not experts on the issue of ONJ or whether ONJ can be caused by Fosamax but the mere fact that they are not experts on the issue of ONJ does not preclude them from testifying as fact witnesses concerning their treatment and the opinions they formed during consultation with Plaintiff. Therefore, in accordance with prior rulings, Dr. Stern is permitted to discuss his knowledge about diabetes and wound healing.

C. Motion To Preclude Testimony that Doctors "Vote" on the Efficacy and Safety of Fosamax with Their Prescription Pads

Here, as in Secrest, Merck represents that it does not intend to argue that physicians "vote with their prescription pads." Therefore, the motion is denied as moot.

D. Motion To Preclude Reference to the Website www.HugeSettlements.com

As Merck does not oppose this motion, it is granted.

E. Motion To Preclude Argument Relating to Evidence Excluded or Limited by the Court

Merck does not oppose this motion and represents that it will "continue to abide by the Court's rulings." The motion is granted.

F. Motion To Preclude Testimony or Argument Inconsistent with the Supreme Court's Holding in Wyeth v. Levine

In accordance with the Court's prior rulings, Merck is precluded from arguing or introducing evidence in support of the proposition that it could not add a warning to or otherwise strengthen Fosamax's label without FDA approval. However, this ruling does not preclude Merck from arguing, or introducing evidence in support of, the proposition that seeking FDA approval before changing a label can be an appropriate or reasonable approach.

G. Motion To Preclude Merck from Introducing Evidence that a Merck Employee or Employee's Family Member Took or Takes Fosamax

This motion is granted in part. Merck may not introduce evidence that its employees or employees' family members used Fosamax. However, should Plaintiff challenge the credibility of a witness who states that Fosamax is safe, then Merck may rehabilitate that witness through evidence that the witness personally used Fosamax. Should Merck intend to conduct such rehabilitation, it must provide Plaintiff with a list of witnesses who have used Fosamax or whose family members have taken the drug.

H. Motion To Preclude Evidence of Merck's "Good Character"

This motion is granted in part. Evidence of Merck's good character is not relevant to this case. However, Merck may offer evidence that it manufactures drugs and that the purpose of these drugs is to treat and to seek to cure diseases, to the extent such evidence provides helpful background information. This ruling permits, among other things, Merck employees to testify about their professional history at Merck beyond just the role they played in developing Fosamax.

I. Motion To Preclude or Limit Evidence Pertaining to Non-ONJ Risks Associated with Plaintiff's Other Prescription Medications or Prior Cigarette Smoking

Defendant represents that it will not seek to argue that smoking is a risk factor for ONJ, but states that Plaintiff's periodontal history and other drug use is relevant to her medical condition. The Court reserves judgment on this issue; certain aspects of Scheinberg's periodontal history and use of other drugs may be relevant, and some may require a limiting instruction. The Court will rule on these specific issues as they arise.

J. Motion To Preclude Merck from Appealing to the Jurors Through "Fear Mongering" and Implying that a Verdict for Plaintiff Takes the Prescription Choice Away from Doctors

Merck agrees that it will not engage in "fear mongering," but the issue of whether Merck can introduce evidence about the larger health consequences of osteoporosis remains. As the Court cannot predict what specific evidence arguments Defendant will introduce, the Court reserves judgment on this motion.

K. Motion To Preclude Merck from Implying that the Court Has a Particular View of the Case

As Merck does not oppose this motion, it is granted.

L. Motion To Preclude Argument or Evidence that Fosamax Reduces Fractures for Non-Osteoporotic Women Without Vertebral Fracture

Plaintiff acknowledges that the Court has previously denied this motion, but repeats it here to "perfect the record." In accordance with prior rulings, this motion is denied.

M. Motion To Preclude Merck from Displaying Microphotographs of Bone Contained in the Dempster Editorial

The Court has previously denied this motion, holding that the editorial from which the microphotograph is taken provides sufficient foundation for what is depicted in the photograph. The microphotograph is relevant because it depicts osteoporosis – a disease Fosamax was designed to prevent. Dr. Dempster's recent deposition does not change the analysis here. The photograph's admissibility is not determined by Dr. Dempster's deposition testimony, but rather is analyzed under the hearsay exception for learned treatises. As this Court has previously found, this photograph is part of a learned treatise and therefore is admissible. See Fed. R. Evid. 803(8).

II. Defendant's Motions in Limine

A. Motion To Preclude Dr. Kraut's Opinions that Were Not Disclosed in the Expert Report or the November 2012 Deposition

Merck's request is denied in part and granted in part. While Dr. Kraut is not permitted to discuss opinions that he did not disclose in his expert report, the Court need not limit his

testimony to the three grounds listed in Merck's motion. Any inconsistencies between deposition and trial testimony are to be explored on cross examination, not motions in limine.

B. Motion To Preclude "Unreliable" Statements of Causation and Diagnosis

Merck is correct that some of the statements made by Plaintiff's treating physicians may not fall under the hearsay exception for medical records. Indeed, Plaintiff must demonstrate that the statement she seeks to admit was pertinent to a medical diagnosis. See Fed. R. Evid. 803(4) (providing a hearsay exception for "statements made for – and reasonably pertinent to – medical diagnosis or treatment and describes medical history; past or present symptoms or sensations; their inception; or their general cause"). The Court reserves judgment on this issue, directing Plaintiff to provide the Court with the statements she wishes to introduce so the Court can make a determination as to their admissibility.

With respect to Scheinberg's proposed testimony about statements made by her doctors, Merck's motion is granted. The question of why Scheinberg stopped taking Fosamax is irrelevant; as Merck notes, there is no dispute on this issue. Therefore, any testimony from Plaintiff that her doctor told her that her injuries were caused by Fosamax would be highly prejudicial and have limited probative value.

C. Motion To Preclude Testimony from Plaintiff's Physicians that They Have Treated Other Patients with Bisphosphonate-Induced ONJ

The motion is granted on the grounds that the proposed testimony from Drs. Stern and Breiman is irrelevant. First, the fact that these doctors have had other patients who contracted ONJ while also on bisphosphonates does not bear on causation. Second, these doctors did not diagnose Scheinberg with ONJ, so their "clinical experience" on how they diagnosed other patients with ONJ is irrelevant to their testimony.

D. Motion To Preclude Evidence of Post-Injury Changes to the Fosamax Label

Merck's motion is in two parts: (1) Merck seeks a ruling that actions taken or not taken by Merck after Scheinberg's injury are inadmissible if offered to show what Merck knew or should have known about the risks of ONJ, and (2) it seeks a ruling from the Court that Plaintiff's injury date is April 30, 2006.

The Court agrees that any conduct undertaken by Merck after Plaintiff's injury is irrelevant. However, the Court denies Merck's request that Plaintiff's "effective" injury date be set as April 30, 2006. Indeed, as Plaintiff's counsel pointed out at oral argument, while actions taken after April 30, 2006 do not go to proximate cause, they go to Merck's continuing duty to warn. Plaintiff is permitted to maintain that her injury date

is December 2006, pursuant to her Amended Plaintiff Profile Form, but Defendant may cross examine her as to the inconsistencies with her original Plaintiff Profile Form.

E. Motion To Preclude Evidence of Adverse Event Reports Dated Later than Merck's Proposed ONJ Precaution Submitted on March 1, 2005

This motion is denied. Adverse event reports received by Merck until the time of Plaintiff's injury are admissible if used as evidence that Merck was on notice of potentially serious jaw injuries. The fact that Merck had already submitted a proposed revised label to the FDA in March does not relieve it of its continuing duty to warn.

F. Motion To Preclude Evidence Relating to Merck's Alleged Duty To Warn Parties Other than Plaintiff's Prescribing Physician

As the Court has granted summary judgment on the breach of warranty claims, this motion is granted.

G. Motion To Preclude Evidence of Marketing Materials Not Directed at Plaintiff's Prescribing Physicians

Plaintiff may not introduce evidence of marketing or promotional materials because she has not established that she or her prescribing physicians were exposed to any such materials. As to Plaintiff's request that the Court permit evidence relating to Merck's "financial influence" of the National Osteoporosis Foundation, the Court reserves judgment on

this issue, as this evidence may be admissible for the limited purpose of impeachment of Dr. Gruber.

H. Motion To Preclude Evidence and Argument Relating to Studies of Concomitant Use of Fosamax with Hormone Replacement Therapy

This motion is granted. A study with the stated purpose of addressing the "safety and efficacy of alendronate combined with HRT in the treatment of post-menopausal osteoporosis" is not relevant to this Plaintiff, in light of her testimony that she never underwent hormone replacement therapy concomitantly with taking Fosamax. Although Plaintiff points out that one or two of the groups included in the study share Plaintiff's characteristics, this fact does not render the study relevant to this Plaintiff.

I. Motion to Preclude Evidence of Regulatory Activities that Post-date Merck's July 2005 Label Change

With respect to statements made at the FDA Advisory Committee meeting, the motion is denied. These statements are public record within the meaning of Rule 803(8) and are relevant to show causation. Merck is permitted to explore the trustworthiness of these statements on cross examination.

With respect to the Medication Guide, the motion is granted. The Court has previously excluded evidence of post-injury label changes under Rule 407. The Medication Guide is properly characterized as a post-injury warning and thus is

inadmissible. Moreover, because the Medication Guide in question involves a subsequent warning, not a repair, Plaintiff's cited authorities are inapposite.

J. Motion To Preclude a Report by the Institute of Medicine

The Institute of Medicine report would only be relevant to rebut Merck's argument that the FDA's inaction demonstrates Fosamax's safety. If Merck does not make this argument, then the report is inadmissible and irrelevant, since it does not specifically address Fosamax.

K. Motion To Preclude Evidence of Regulation of Fosamax in Foreign Jurisdictions

At oral argument, Plaintiff represented that it would seek to admit evidence as to the Canadian label for Fosamax. As long as the labeling in question pre-dates Plaintiff's injury, this evidence is admissible.

L. Motion To Preclude Articles Co-authored by PSC

This motion is granted in part and denied in part, consistent with prior rulings. Any statements in the Edwards Article and Guyatt Article that have already been precluded through Daubert are inadmissible, but other portions of the articles may be admitted, if they are relevant.

M. Motion To Preclude Evidence that CTX Testing Is a Predictor of ONJ Risk

Plaintiff stipulates to this motion, so long as the CTX evidence exclusion is reciprocal. The Court has addressed the CTX issue in its Daubert ruling, and held that expert witnesses can rely on any literature and hearsay in making opinions, but may not cite it to the jury. Therefore, the motion is granted.

N. Motion To Preclude Evidence of Merck's Alleged Motives

Consistent with prior rulings, this motion is granted, as the prejudice that could result from this evidence substantially outweighs the probative value.

O. Motion To Preclude Evidence of Studies Considered but Not Conducted by Merck

This motion is denied. The issue of Merck's pharmacovigilance, or alleged lack thereof, is admissible to rebut Defendant's arguments. Indeed, if Merck is permitted to argue that it relied on a lack of evidence about ONJ and prolonged Fosamax use, then Plaintiff should be permitted to present the jury with a fuller picture of why Merck had no such evidence.

P. Motion To Preclude Articles About the Cost-Effectiveness of Alendronate Therapy

This motion is denied. If Plaintiff demonstrates the relevance of this article, it will be admissible. Merck can

address the "limitations" of the study during its examination of the witness.

Q. Motion To Preclude Testimony or Evidence Regarding the "Mucci Review"

Merck has not introduced any new facts that would cause the Court to depart from its rulings in prior bellwether trials. This motion is denied and the "Mucci Review" is admissible as a business record under Federal Rule of Evidence 803(6).

R. Motion To Preclude Warning, Inquiry, and Untitled Letters from the FDA

This issue is granted in part and denied in part. First, the Court adheres to its prior ruling that the "DDMAC letters are not admissible to show that the plaintiff or prescribing doctor were misled by the advertising materials at issue in the letters" because Plaintiff has failed to establish that either she or any of her prescribing physicians ever saw any material that was the subject of correspondence between DDMAC and Merck. With respect to Plaintiff's argument that these letters are admissible to show that Merck was "on notice" about the limits of Fosamax's efficacy, the Court notes that the DDMAC's role belies that suggestion. As the DDMAC "reviews and regulates promotional materials and activities for prescription drug products," it could not reasonably be perceived to provide Merck with information – or notice – related to efficacy issues.

Consistent with prior rulings, the Court further directs that if Plaintiff wishes to use these letters in rebuttal, the Court and Defendant must be so advised 24 hours ahead of time, at which time the Court will review the letter Plaintiff seeks to introduce.

S. Motion To Preclude Emails from Non-Merck Employees Regarding Limitations of Fosamax's Efficacy

This motion is denied. Plaintiff represents that the email in question is not being offered for the truth, but rather to demonstrate that Merck should have been on notice of the problems with its efficacy studies. As the Court has discussed in II.D and II.E, above, the fact that Merck proposed a label change does not absolve it of its continuing duty to warn. Therefore, the email is admissible.

T. Motion To Preclude Testimony by Dr. Parisian Regarding Suppression of Bone Turnover, the Mechanism or Etiology of ONJ and Duration of Use

In accordance with prior rulings, the Court holds that Dr. Parisian's commentary on any documents and exhibits in evidence will be limited to explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge.

U. Motion To Preclude Any Testimony or Evidence Discussing How the FDA Is Funded

This motion is granted. As the Court has previously found, the question of funding of the FDA is not properly in the case, and any testimony relating to it is excluded.

III. Undisputed Motions

Merck has made eleven additional motions, listed below, without argument, and Plaintiff has not opposed them. The following motions, numbered in accordance with Merck's motion papers, are granted.

20. VIOXX.
21. Any References To Other Fosamax Cases.
22. "Bad Act" Testimony Presented As Expert Testimony.
23. Employees Allegedly Leaving Merck "Because" Of Fosamax Or Fosamax Litigation.
24. National Public Radio Story.
25. Defense Counsel Or Jury Consultants.
26. Liability Insurance.
28. Photographs Or Written Descriptions Of ONJ In Non-Oral Bisphosphonate Users.
29. Phossy Jaw.
30. Ghostwriting.
31. Alternative Uses for Bisphosphonates.

SO ORDERED.

Dated: New York, New York
January 15, 2013

John F. Keenan
United States District Judge